

General

Guideline Title

An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma

Bibliographic Source(s)

Bulger EM, Snyder D, Schoelles K, Gotschall C, Dawson D, Lang E, Sanddal ND, Butler FK, Fallat M, Taillac P, White L, Salomone JP, Seifarth W, Betzner MJ, Johannigman J, McSwain N. An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma. Prehosp Emerg Care. 2014 Apr-Jun;18(2):163-73. [44 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions of the strength of recommendations (Strong, Weak) are provided at the end of the "Major Recommendations" field.

Tourniquets

Recommendation 1: The panel recommends the use of tourniquets in the prehospital setting for the control of significant extremity hemorrhage if direct pressure is ineffective or impractical.

Strength of Recommendation: Strong

Quality of Evidence: Moderate. The overall quality of the evidence for survival benefits of tourniquet use was upgraded from Low to Moderate, based on the large effect size. The evidence for preventing amputation was very low, due to a smaller effect size and issues relating to confounding (see Table 2 in the original guideline document).

Remarks: The panel believes that tourniquets used to treat severe extremity hemorrhage have a clear survival benefit, demonstrated by a large and consistent effect size across several studies. The panel discussed that direct pressure may be ineffective in the setting of major arterial injury or impractical in circumstances with limited manpower, unsecure scene, or when complex extrication or extraction is required.

Recommendation 2: The panel suggests using commercially produced windlass, pneumatic, or ratcheting devices that have been demonstrated to occlude arterial flow.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impede venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications.

Recommendation 3: The panel suggests against the use of narrow, elastic, or bungee-type devices.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impede venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications.

Recommendation 4: The panel suggests that improvised tourniquets be applied only if no commercial device is available.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: The panel discussed the military experience with varying types of tourniquets and felt that tourniquet selection should be based on proven effectiveness at arterial occlusion. Tourniquets that impeded venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications. Commercially available tourniquets are favored over improvised tourniquets unless there is no other option.

Recommendation 5: The panel suggests against releasing a tourniquet that has been properly applied in the prehospital setting until the patient has reached definitive care.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: Given the relatively short transport times for most civilian emergency medical services (EMS) agencies, the committee felt the safest option was to leave a tourniquet that had been placed in the field in place until the patient can be assessed in the hospital. There may be exceptions to this approach for prolonged transport times or austere environments. In these circumstances, prehospital providers should consult direct (online) physician medical direction.

Junctional Hemorrhage Devices

Regarding the questions related to junctional hemorrhage devices, the panel believes this is an important area for further study, but did not find sufficient evidence to make a recommendation at this time.

Topical Hemostatic Agents

Recommendation 1: The panel suggests the use of topical hemostatic agents, in combination with direct pressure, for the control of significant hemorrhage in the prehospital setting in anatomic areas where tourniquets cannot be applied and where sustained direct pressure alone is ineffective or impractical.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: While the evidence was low, there are consistent data from animal models, suggesting reduced hemorrhage with these agents compared to standard gauze and the committee felt that junctional hemorrhage and torso wounds may benefit from the combination of direct pressure and hemostatic dressings.

Recommendation 2: The panel suggests that topical hemostatic agents be delivered in a gauze format that supports wound packing.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: This recommendation was based on the military experience and the animal studies suggesting that products that allow packing of the wound have superior hemorrhage control.

Recommendation 3: Only products determined effective and safe in a standardized laboratory injury model should be used.

Strength of Recommendation: Weak

Quality of Evidence: Low

Remarks: The U.S. Army Institute for Surgical Research has developed a standardized large animal model for comparison of hemostatic dressings. The committee felt that all new products should be subject to this testing.

Definitions:

Using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) terminology, strong recommendations begin with the words "the panel recommends" and indicate that the panel believes that the benefits clearly outweigh any risks associated with the treatment and that nearly all informed patients would want the recommended treatment. Weak recommendations begin with the words "the panel suggests," which indicates that the panel had a higher level of uncertainty about estimated benefits of the treatment the balance between benefits and risks.

Clinical Algorithm(s)

An algorithm titled "Prehospital External Hemorrhage Control Protocol" is provided in the original guideline document.

Scope

Disease/Condition(s)

External hemorrhage

Guideline Category

Management

Treatment

Clinical Specialty

Critical Care

Emergency Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Emergency Medical Technicians/Paramedics

Hospitals

Nurses

Physician Assistants

Guideline Objective(s)

To develop evidence-based guidelines for the use of tourniquets and hemostatic dressings in the U.S. civilian prehospital setting

Target Population

Individuals with extremity hemorrhages

Interventions and Practices Considered

- 1. Tourniquets
 - Commercially produced windlass, pneumatic, or ratcheting devices
 - Improvised tourniquets only if no commercial device is available
- 2. Not releasing a properly applied tourniquet in the prehospital setting until patient has reached definitive care
- 3. Topical hemostatic agents
 - In combination with direct pressure
 - In gauze format that supports wound packing
- 4. Use of only products determined effective and safe in standardized laboratory injury model

Note: The following interventions were considered but not recommended:

Narrow, elastic, or bungee-type devices Junctional hemorrhage devices

Major Outcomes Considered

- Limb salvage
- Hypovolemic shock
- Survival
- Adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature search included 13 external and internal electronic databases, including CINAHL, EMBASE, and MEDLINE, from 2001 to 9/12/2013 for fully published, primary, clinical studies. The Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment and Database (HTA) were also searched for secondary reviews. Additional search steps included manual search of bibliographies listed in fully published studies; search and written inquiry to regulatory agencies, including the U.S. Food and Drug Administration; and search of www.ClinicalTrials.gov and www.controlled-trials.com for ongoing clinical trials. Publications were also suggested for inclusion by expert panel members who commented on

the draft report.

The criteria for inclusion in the systematic review were studies published in English that reported on traumatic hemorrhage treated by Emergency Medical System (EMS) personnel in the prehospital setting with tourniquets or hemostatic dressings currently available in U.S. commercial markets. In addition, the studies reported findings on at least one of the outcomes identified in the populations, interventions, comparators, outcomes, timing, and settings (PICOTS) questions and included at least 5 patients per treatment group; results for extremity and junctional hemorrhage were considered separately. To avoid duplication, when several sequential reports from the same study center were available, only findings from the largest, most recent, or most complete report was used. Because of the paucity of published studies on hemostatic dressings, for these questions the inclusion criteria were expanded to include animal studies of U.S. Food and Drug Administration (FDA)-cleared or approved hemostatic dressings using either a swine or goat model of extremity bleeding. Risk of bias and other indicators of strength of evidence were assessed and reported.

For more information see the evidence report (see the "Availability of Companion Documents" field).

Number of Source Documents

- 23 clinical studies
 - 16 studies of tourniquets
 - 7 clinical studies of hemostatic dressings
- 9 studies with human volunteers
- 3 simulation studies
- 39 animal model studies

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The overall strength of evidence for each key question and outcome was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) principles. The strength of evidence grade is a composite of the study design, study limitations (risk of bias), consistency, directness, precision, and publication bias domains. These strength of evidence grades are described as High, Moderate, Low or Very Low and reflect decreasing confidence in the estimates of the effects of interventions on outcomes.

Although the initial assignment of a strength of evidence rating is based on study design, GRADE allows the evidence appraisal to be upgraded or downgraded, depending on such factors as the size and consistency of the reported effect or the presence of a dose response.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The absolute risk differences and relative risk (RR) with 95% confidence intervals for the primarily dichotomous outcomes were calculated for individual studies. In cases in which meta-analysis was possible a summary odds ratio (OR) was calculated using a random effects model. Studies were combined using meta-analysis when populations and interventions were similar. Given the nature of the populations examined in this report, military populations were separated from civilian populations and data from children (younger than 18 years of age) was also examined independently. Statistical heterogeneity was examined using I^2 , but the small number of studies in the comparisons limited our confidence in measures of heterogeneity.

For more information, see the evidence report (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Expert Panel

An expert panel was convened by the American College of Surgeons Committee on Trauma EMS Committee to include nationally recognized experts in prehospital trauma care. Representatives were included from the military's Tactical Casualty Combat Care Committee, Prehospital Trauma Life Support, civilian State Emergency Medical System (EMS) directors, trauma surgeons, emergency physicians, a pediatric surgeon, an EMS researcher, a Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodologist, and a paramedic.

Representatives were from both the United States and Canada. Panelists provided input to the formulations of the populations, interventions, comparators, outcomes, timing, and settings (PICOTS) questions prior to the initiation of the literature review. For the PICOTS questions, the population of interest was defined to be individuals with extremity hemorrhages; the interventions were commercially available tourniquets and hemostatic dressings; comparators were external wound pressure and nontourniquet or nonhemostatic interventions; outcomes of interest were limb salvage, hypovolemic shock, survival, and adverse effects. Because timing and setting were considered to be key aspects of the investigation the PICO format was expanded to include both immediate and long-term outcomes and the setting for the intervention was defined as the prehospital environment, before any procedures are performed in the hospital emergency department or operating theater. Following the completion of the systematic literature review, the panel met to review the literature in a full day meeting in Washington DC, on October 6, 2013. An expert in the application of the GRADE methodology facilitated the meeting and the panel used this approach to develop recommendations for each PICOTS question.

Evidence Review

A systematic review of the literature was conducted by ECRI Institute, one of the eleven Evidence-Based Practice Centers (EPC) designated by
the U.S. Agency for Healthcare Research and Quality. Their systematic literature review and evidence tables were used by the expert panel to
develop these recommendations. A summary of the findings is included in the original guideline document; the full ECRI report will be
simultaneously published by the National Highway Traffic Safety Administration (NHTSA) and will be available at www.ems.gov
. The PICOTS questions used to guide the literature review were developed with input from the multidisciplinary expert
panel.

PICOTS Questions

- 1. In trauma patients with extremity hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting, what is the effect of tourniquet use (single or double) with or without external wound pressure on limb salvage, hypovolemic shock, survival, and adverse effects compared with external pressure alone or with other nontourniquet interventions?
- 2. In trauma patients with junctional hemorrhage who are treated in the prehospital setting, what is the effect of junctional hemorrhage control device use with or without external wound pressure on limb salvage, hypovolemic shock, survival, and adverse effects compared with external pressure alone?
- 3. In trauma patients with extremity hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting, do different brands or models of tourniquets differ from each other in their effect on limb salvage, hypovolemic shock, survival, and adverse effects?
- 4. In trauma patients with junctional hemorrhage who are treated in the prehospital setting by EMS personnel, do different brands or models of specialized junctional hemorrhage control devices differ from each other in their effect on limb salvage, hypovolemic shock, survival, and adverse effects?
- 5. In trauma patients with external hemorrhage (excludes junctional hemorrhage) who are treated in the prehospital setting using a tourniquet
 - a. Does the incidence of adverse events vary by the duration of tourniquet use prior to removal?
- b. Does the incidence of adverse events vary depending on whether tourniquets are removed in the field versus in a facility?6. In trauma patients with external hemorrhage (hemorrhage from any body surface) who are treated in the prehospital setting, what is the
- effect of hemostatic dressings with or without external wound pressure on, control of hemorrhage, limb salvage (if an extremity involved), hypovolemic shock, survival, and adverse effects compared with using non-hemostatic gauze with or without external wound pressure?
- 7. In trauma patients with external hemorrhage (hemorrhage from any body surface) who are treated in the prehospital setting, do different brands or types of hemostatic dressings differ from each other in their effect on, hemorrhage control, limb salvage (if an extremity is involved), hypovolemic shock, survival, and adverse effects?

GRADE Methodology

The panel used the GRADE methodology to guide the process of PICOTS question formulation, evidence appraisal, and to designate the strength of recommendations. The process also adhered to the National Prehospital Evidence- Based Guideline (EBG) Model Process approved by the Federal Interagency Council for EMS and the National EMS Advisory Council. Panel members received an introduction to the GRADE methodology and reviewed the evidence for structured clinical questions using the PICO framework. After reading and discussing the systematic review of the evidence, the panel drafted graded recommendations.

Rating Scheme for the Strength of the Recommendations

Using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) terminology, strong recommendations begin with the words "the panel recommends" and indicate that the panel believes that the benefits clearly outweigh any risks associated with the treatment and that nearly all informed patients would want the recommended treatment. Weak recommendations begin with the words "the panel suggests," which indicates that the panel had a higher level of uncertainty about estimated benefits of the treatment the balance between benefits and risks.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of trauma patients with extremity hemorrhage treated in the prehospital setting

Potential Harms

- Tourniquets that impede venous return without adequate arterial occlusion may only worsen hemorrhage and increase complications.
- The primary adverse event noted in studies of hemostatic dressings was pain and discomfort associated with an exothermic reaction to QuickClot granules.
- Adverse events associated with prehospital tourniquet (see Table 9 in the evidence report [see the "Availability of Companion Documents" field])
- Potential adverse events associated with tourniquet use (such as myonecrosis, nerve palsy, increased pain, infection, and thrombosis) and hemostatic dressings (such as burns, allergic reactions, infections, and tissue damage)

Qualifying Statements

Qualifying Statements

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Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Bulger EM, Snyder D, Schoelles K, Gotschall C, Dawson D, Lang E, Sanddal ND, Butler FK, Fallat M, Taillac P, White L, Salomone JP, Seifarth W, Betzner MJ, Johannigman J, McSwain N. An evidence-based prehospital guideline for external hemorrhage control: American College of Surgeons Committee on Trauma. Prehosp Emerg Care. 2014 Apr-Jun;18(2):163-73. [44 references] PubMed

Not applicable: The guideline was not adapted from another source.
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The authors report no conflicts of interest.
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This is the current release of the guideline.
Guideline Availability
Electronic copies: Available from the National Association of Emergency Medical Technicians Web site
Availability of Companion Documents
The following is available:
• Snyder D, Tsou A, Schoelles K. Efficacy of prehospital application of tourniquets and hemostatic dressings to control traumatic external hemorrhage. Evidence report. Washington (DC): National Highway Traffic Safety Administration; 2014 May. 147 p. Electronic copies: Available from the National Highway Traffic Safety Administration Web site
Patient Resources

NGC Status

This NGC summary was completed by ECRI Institute on July 23, 2014. The information was verified by the guideline developer on July 25, 2014.

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